510(k) Summary
Paragonix Sherpa Pak Cardiac Transport System

FEB 0 6 2013

Submitter:	Paragonix Technologies, Inc. Fifth Floor 2 Canal Street Cambridge, MA 02141 Phone: 617. 817.7790 Fax: 617.812.3057
Contact Person:	Leo Basta NorthStar Biomedical Associates 755 Westminster St., Unit 120 Providence, RI, 02903 Phone: 617.834.9866 lbasta@northstarbiomedical.com
Date Prepared:	October 24, 2012
Trade Name:	Paragonix Sherpa Pak Cardiac Transport System
Classification Name:	System & Accessories, Isolated Heart, Transport & Preservation
Regulation Number:	21 CFR 876.5880
Product Code:	MSB
Predicate Devices:	Lifeport Kidney Transport System (K021362) Avid Custom Procedure Tray [Class I 510(k) Exempt] Celsior Cold Flush Storage and Transport Solution for Hearts (K991594)
Device Description:	The Paragonix Sherpa Pak Cardiac Transport System is a device intended to provide a safe, consistent method for cold ischemic storage and transport of donor hearts to recipients for transplantation. The Sherpa Pak System consists of 1) an outer shipper which contains various non-ice based temperature controlled packaging elements, 2) an inner and outer hard shell container (i.e. Sherpa Pak/Sherpa Pak Shell)

which provides a double, rigid barrier container in which the heart is immersed and suspended in a Cold Storage Fluid cleared for use in storing and transporting donor hearts and 3) a temperature display and timer to monitor temperature and elapsed time of transport, respectively.

Intended Use: Organ storage and preservation for transplantation.

Indications for Use: The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts, up to 4 hours, during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the heart.

Functional Testing: Descriptive information, laboratory bench testing, and biocompatibility testing were provided to demonstrate the device meets its design specifications, performs as intended, and is safe for its intended use. Specifically, testing to demonstrate that the Sherpa Pak System provided a transport system robust enough to protect the heart during transport and maintained temperature throughout the duration of transport, was included. In addition, biocompatibility testing including cytotoxicity, systemic toxicity, genotoxicity, sensitization, and intracutaneous testing was performed.

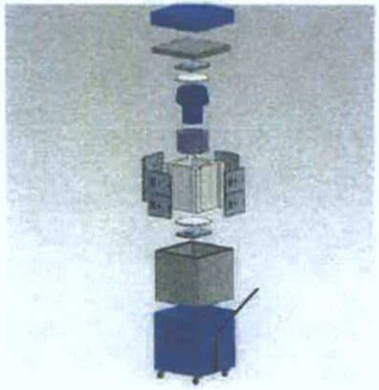
K123326
Page 3 of 6

0019

Device Characteristic Comparison

Characteristic	Proposed Sherpa Pak Cardiac Transport System Device [current 510(k)]	Celsior Cold Storage Solution – K991594	Lifeport Kidney Transporter – K021362	Avid Medical Custom Procedure Tray Class I 510(k) Exempt
Intended Use	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation.	Organ storage and preservation for transplantation
Indications for Use	"The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts, up to 4 hours, during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the heart."	"Celsior is intended for flushing and cold storage of a heart at the time of its removal from a donor in preparation for storage, transportation, and eventual transplantation into a recipient."	"LifePortTM, Kidney Perfusion Transporter (KTR) is intended to be used for the continuous hypothermic machine perfusion of kidneys for the preservation, transportation and eventual transplantation into a recipient."	Specific indication statement is unknown. However, the Avid procedure tray is sold to an organ procurement center, Avid NEOB0005-03, for heart packaging with Celsior Cold Storage Solution for transportation to recipient for transplantation.
Regulation Number	878.5880	878.5880	878.5880	876.4800
Product Code	MSB	MSB	KDN	KDD
Device Classification Name	Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	Device Classification Name – System & Accessories, Isolated Heart, Transport & Preservation	System, Perfusion, Kidney	Kit, surgical instrument, disposable.
Mode of Operation	Static cold ischemic storage	Static cold ischemic storage	Cold ischemic perfusion storage	Static cold ischemic storage
Meets UNOS Policy 5[1]	Yes	Yes	Yes	Yes

[1] http://www.optn.transplant.hrsa.gov

Characteristic	Proposed Sherpa Pak Cardiac Transport System Device [current 510(k)]	Celsior Cold Storage Solution – K991594	Lifeport Kidney Transporter – K021362	Avid Medical Custom Procedure Tray – Class I 510(k) Exempt
Organ container	Two rigid airtight containers one of which contains the cold storage solution in which the heart is immersed .	None. Solution is used by organ procurement centers in various containers or bags.	Cassette well with top.	Plastic tub with lid and bags.
Cooling	Preconditioned storage solution and temperature controlled packaging including preconditioned phase change material cold packs, PIR insulating panels, and Expandable Polystyrene panels	Preconditioned. Relies on transport system for type of cooling and maintenance of temperature	Preconditioned storage solution, ice and water. Case has insulated cover.	Preconditioned storage solution, ice and water. Requires use of a commercial cooler (e.g., igloo style).
System components	 • Outer plastic corrugated container (top and base with wheels) • PIR insulating panels • PCM Cold Pack Panels • EPS panels • Sherpa Pak and Sherpa Pak Shell with heart connector • Temperature data logger • Timer	 • Plastic bag with cold storage solution to be used in combination with some type of organ transport container (e.g., such as the Avid custom procedure kit and off-the-shelf cooler).	 • Ice container • Cassette • Insulating cover • Infusion pump • Cannula • Control panel • Batteries • Pressure sensor • Organ cradle	 • 64 oz. tub with lid • Polyethylene bags • Procedure wrap • Twill tape Once heart is packaged, kit is stored on ice in a standard cooler.

Characteristic	Proposed Sherpa Pak Cardiac Transport System Device [current 510(k)]	Celsior Cold Storage Solution – K991594	Lifeport Kidney Transporter – K021362	Avid Medical Custom Procedure Tray – Class I 510(k) Exempt
Single Use/Reuse	Entire system is single use/patient only.	Single use/patient only.	Some components are single use/patient only; others are reusable.	Single use/patient only. Commercial cooler may be reused.
Sterilization	Sherpa Pak, Sherpa Pak Shell, and Heart connector are sterilized by gamma irradiation. All other components are non-sterile.	Sterilized.	Disposable accessories are EO sterilized; other components are non-sterile.	EO sterilized.
Biocompatibility	Direct and indirect heart contact materials have been tested for biocompatibility.	Yes.	Kidney contact materials have been tested for biocompatibility.	Unknown.
Intended storage time	Up to 4 hours (clinical standard is 4 – 6 hours)	Unspecified.	Unspecified	Unspecified

Summary of Substantial Equivalence:

The design, intended use, principles of operation, and technological characteristics of the Sherpa Pak Cardiac Transport System are substantially equivalent to those of the predicate devices cited above. Substantial equivalence is based upon descriptive characteristics of the various cited predicate devices and upon the testing conducted to demonstrate that the subject device performs as intended and is substantially equivalent to the predicate devices in terms of its ability to safely store and transport a donor heart at a clinically acceptable temperature range to a recipient for transplantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2013

Paragonix Technologies, Inc.
% Mr. Leo Basta
Owner
NorthStar Biomedical Associates
755 Westminister Street Unit 120
PROVIDENCE RI 02903

Re: K123326
Trade/Device Name: Paragonix Sherpa Pak Cardiac Transport System
Regulation Number: 21 CFR§ 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: MSB
Dated: December 17, 2012
Received: December 20, 2012

Dear Mr. Basta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K123326

Device Name: Paragonix Sherpa Pak Cardiac Transport System

Indications for Use:

The Sherpa Pak Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts, up to 4 hours, during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the heart.

Prescription Use: X AND/OR Over-The Counter Use:

(Per 21 CFR 801 Subpart D)..... (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123326